K051880

JAN 4 2006

Section 5 — 510(k) Summary

510(k) Summary

5.1 General Provisions

Submitter's Name and Address	Boston Scientific Corporation 2011 Stierlin Court Mountain View, CA 94043-4655, U.S.A.
Contact Person	Catherine A. Peters Regulatory Affairs Specialist Tel: (650) 623-1755 Fax: (650) 623-1610
Classification Name	Embolectomy Catheter, 21 CFR 870.5150
Common or Usual Name	Embolectomy Catheter
Proprietary Name	Boston Scientific Rio™ Aspiration Catheter
Manufacturing Facilities	Boston Scientific Corporation 2011 Stierlin Court Mountain View, CA 94043-4655, U.S.A.

5.2 Name of Predicate Device

Vascular Solutions, Inc. Pronto™ Extraction Catheter (K032763)
Medtronic, Inc. Export™ Catheter (K040869 and K050139)

5.3 Device Description

The Rio Aspiration Catheter ("Rio") is a single use, dual lumen aspiration catheter. The usable length of the catheter is 145 cm. The Rio catheter is intended for use with a 0.014" guide wire or a FilterWire EZ protection wire, and can be accommodated in a 6F guide catheter with a minimum inner diameter of 0.070 inches (1.78 mm).

The primary aspirate lumen of the Rio catheter acts as a conduit for thrombus removal and extraction. Thrombus enters the distal catheter tip, and is drawn through the lumen and deposited into a proximal vacuum source, a 20 cc syringe. On the proximal end of the catheter is a standard female luer fitting, which attaches to the syringe via an extension line and stopcock.

The secondary, shorter monorail lumen is a distal tubular segment designed for the insertion of and tracking over conventional 0.014" diameter guidewires or the Boston Scientific FilterWire EZ™ protection wire.

The Rio catheter shaft is comprised of stiffer proximal and more flexible distal sections to facilitate flexibility and trackability of the catheter during advancement into the vessel. The tip of the catheter is designed with a taper to reduce trauma and facilitate aspiration. A radiopaque marker is placed 0.5 mm from the distal tip of the device to aid in visualization under fluoroscopy.

5.4 Intended Use

The Rio Aspiration Catheter is indicated for the removal of fresh, soft thrombi from vessels in the arterial system.

5.5 Summary of Technological Characteristics

The design of the Rio Aspiration Catheter ("Rio") is substantially equivalent to that of the Pronto™ Extraction Catheter and Export™ Catheter. Like the Pronto and Export catheters, the Rio catheter is designed for the removal of fresh, soft thrombi from vessels of the arterial system via a dual lumen monorail catheter system incorporating a syringe and extension line for vacuum capability. Testing performed on the Rio Aspiration Catheter confirms that the Rio catheter will perform as intended.

5.6 Non-Clinical Test Summary

Where appropriate, testing conformed to the requirements of 21 CFR Part 58 [Good Laboratory Practices (GLP)]. Specifically, non-clinical tests conducted for the Rio Aspiration Catheter showed the device met its design-input criteria, and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 4 2006

Ms. Catherine A. Peters
Regulatory Specialist II
Boston Scientific Corporation
2011 Stierlin Court
Mountain View, CA 94043-4655

Re: K051880
Trade/Device Name: Rio Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: DXE
Dated: December 23, 2005
Received: December 27, 2005

Dear Ms. Peters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3 — Indications For Use

Device Name: Boston Scientific Rio™ Aspiration Catheter

510(k) Number (if known): K051880

Indications for Use:

The Rio Aspiration Catheter is indicated for the removal of fresh, soft thrombi from vessels in the arterial system.

Prescription Use ____X_____ OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K051880